CLAIMS

1. A medical device, comprising:
   a barrel having an open proximal end and a distal end;
   a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
   a cartridge in fluid communication with the needle, comprising:
      a first chamber containing a first substance;
      a second chamber containing a second substance;
      a fluid flow controller between the first chamber and the second chamber; and
   a plunger slidably disposed within the cartridge;
   a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
   a needle retainer releasably retaining the needle in the extended position;
   wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and continued advancement of the plunger and cartridge relative to the barrel after the mixture is expelled from the cartridge actuates the needle retainer to release the needle, whereupon the biasing element displaces the needle relative to the barrel to shield the first sharpened tip.

2. The medical device in claim 1 wherein the medical device further comprises a needle carrier fixed to the needle.

3. The medical device in claim 1 wherein the needle has a second sharpened tip at its rearward end.

4. The medical device in claim **1** wherein the needle is retracted upon release of pressure on the plunger.

5. The medical device in claim **1** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened needle tip beyond the proximal end of the barrel as the needle is moved to the shielded position.

6. The medical device in claim **1** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

7. The medical device in claim **1** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

8. The medical device in claim **1** wherein the second substance is a powdered material.

9. The medical device in claim **1** wherein the second substance is a liquid material.

10. The medical device in claim **1** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

11. The medical device in claim **1** wherein the fluid flow controller comprises:

a wall between the first and second chambers having an opening;

a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber; and

a fluid flow pathway through the piercing element;

wherein axially displacing the cartridge toward the barrel displaces the plunger until the plunger is ruptured by the piercing element,

creating a passage through the plunger which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the plunger into the second chamber.

12. The medical device in claim **1** wherein the fluid flow controller comprises:

a barrier between the first and second chambers having an opening;

a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber;

a fluid flow pathway through the piercing element; and

a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;

wherein axially displacing the plunger toward the barrel displaces the pierceable mid seal until the mid seal is ruptured by the piercing element, creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

13. The medical device in claim **1** wherein the fluid flow controller comprises:

a mid seal between the first and second chambers that is axially displaceable within the cartridge; and

an elongated fluid passage in the side wall of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

14. The medical device in claim **1** wherein the cartridge is substantially permanently attached to the barrel.

15. The medical device in claim **1** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

16. The medical device in claim **2** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

17. The medical device in claim **2** wherein the needle retainer comprises a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage a pair of windows in the barrel wall.

18. The medical device in claim **2** wherein a cylindrical sleeve having generally the same outside diameter as the cartridge is disposed around the circumference of the needle carrier in general axial alignment with the cartridge, such that axial advancement of the cartridge at the end of the injection stroke displaces the sleeve toward the distal end of the barrel to actuate the needle retainer.

19. The medical device in claim **3** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

20. The medical device in claim **19** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

21. The medical device in claim **19** wherein the distal end of the front seal

includes an external thread and the proximal end of the needle carrier includes a cavity adapted to receive the threaded end of the front seal.

22. A medical device, comprising:

a barrel having an open proximal end, a distal end and an opening through the barrel wall oriented perpendicularly to the longitudinal axis of the barrel;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller connecting the first chamber and the second chamber; and

a plunger slidably disposed within the cartridge;

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip;

a needle retainer releasably retaining the needle in the extended position; and

a locking clip detachably connected to the barrel;

wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and removal of the locking clip from the barrel permits further advancement of the plunger and cartridge relative to the barrel to expel the mixture from the second chamber, whereafter axially advancing the cartridge disengages the needle retainer to allow the biasing element to displace the needle relative to the barrel to shield the first sharpened tip.

23. The medical device in claim **22** wherein the medical device further comprises a needle carrier fixed to the needle.

24. The medical device in claim **22** wherein the needle has a second sharpened tip at its rearward end.

25. The medical device in claim **22** wherein the needle is retracted upon release of pressure on the plunger.

26. The medical device in claim **22** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

27. The medical device in claim **22** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened tip beyond the open proximal end of the barrel as the needle is moved to the shielded position.

28. The medical device in claim **22** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

29. The medical device in claim **22** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

30. The medical device in claim **22** wherein the locking clip comprises a flat U- shaped disk having a plurality of teeth along the inner edge, said clip being configured to slide through the slits in the barrel in a direction perpendicular to the longitudinal axis of the barrel and at a location between the cartridge and the needle retainer, thereby impeding

contact between the cartridge and the needle retainer.

31. The medical device in claim **22** wherein the second substance is a powdered material.

32. The medical device in claim **22** wherein the second substance is a liquid material.

33. The medical device in claim **22** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

34. The medical device in claim **22** wherein the fluid flow controller comprises:

a barrier between the first and second chambers having an opening;

a hollow piercing element disposed through the opening having a sharpened end extending within the first chamber;

a fluid flow pathway through the piercing element; and

a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;

wherein initial axial displacement of the plunger toward the barrel displaces the pierceable mid seal into contact with the piercing element, piercing the mid seal and creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

35. The medical device in claim **22** wherein the fluid flow controller comprises:

a mid seal between the first and second chambers that is axially displaceable within the cartridge; and

an elongated fluid passage in the side wall of the cartridge between the

mid seal and the distal end of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

36. The medical device in claim **23** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

37. The medical device in claim **23** wherein the needle retainer comprises a pair of forward windows in the barrel wall and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows.

38. The medical device in claim **24** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

39. The medical device in claim **38** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

40. A medical device, comprising:

a barrel having an open proximal end and a distal end;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller between the first chamber and the second chamber; and

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and

a needle retainer releasably retaining the needle in the extended position;

wherein the fluid flow controller is adapted to keep the first and second substances separate prior to use, and also adapted to allow mixing of the first and second substances prior to an injection, wherein after use the needle is disposed in the shielded position.

41. A method for injecting medicine, comprising the steps of:

providing an injection device having a first chamber containing a first medicinal component, a second chamber containing a second medicinal component, and a needle;

transferring the first medicinal component from the first chamber to the second chamber;

mixing the first and second components to form a medicinal mixture;

expelling the medicinal mixture from the chamber; and

retracting the needle after expelling the medicinal fluid to shield the needle against contact.